

## REMARKS/ARGUMENTS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendments and remarks herewith, which place the application into condition for allowance. The present amendment is being made to facilitate prosecution of the application.

### I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 1-14 are currently pending. Claims 1, 10 and 11 are independent and are hereby amended. No new matter has been introduced. Support for this amendment is provided throughout the Specification as originally filed.

Changes to the claims are not made for the purpose of patentability within the meaning of 35 U.S.C. §101, §102, §103, or §112. Rather, these changes are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

### II. REJECTIONS UNDER 35 U.S.C. §102

Claims 1-7, 9-12, and 14 were rejected under 35 U.S.C. §102 as allegedly anticipated by U.S. Patent No. 6,259,946 to Higo et al. (hereinafter, merely Higo).

Applicants respectfully traverse this rejection.

Independent claim 1 is representative and recites, *inter alia*:

“a sheet member **composed of a porous material** . . . having a property for allowing said gel to permeate therein,

... .

wherein, when said gel is disposed on said sheet member in the region to receive the gel, the property of the sheet member to allow the gel to permeate therein is sufficient to

provide a retention force resulting from a permeated portion of the gel to retain the gel in the region to receive the gel.” (emphases added)

Claim 1 has been amended to characterize the sheet member as being made of a porous material. Publ. App. par. [0008]. The porous sheet member of the present invention as claimed in claim 1 is distinguishable from the *Higo* reference.

The Office Action states the support (2) of *Higo* corresponds to the sheet member (50) of the present application. First, the Office Action misstates the composition of the support (2) of the *Higo* reference. The material composition of *Higo*'s support (2) is popular polymer which does not involve non-woven fabric and neither does the material “hav[e] a property for allowing said gel to permeate therein” as recited in claim 1. Second in the *Higo* device, an electrolyte layer is only fitted into the concave part of a cup-shaped support (*Higo*, col. 2, lines 64-65). Therefore, *Higo*'s reference fails to disclose the claimed sheet member and the effective function as recited in claim 1.

In the Office Action at page 4, “Response to Arguments,” fails to address the limitation on the support member as recited in the “wherein” clause claim 1. The “wherein” clause recites, “when said gel is disposed on said sheet member in the region to receive the gel, the property of the sheet member to allow the gel to permeate therein is sufficient to provide a retention force resulting from a permeated portion of the gel to retain the gel in the region to receive the gel.” Applicants contend this language places a structural limitation on the composition of the sheet member that restricts the sheet member to only certain materials. In particular, the sheet member must be of a material that permits the gel to permeate therein and, moreover, the retention force developed by the permeation is sufficient to retain the gel in the device.

The Office Action also asserts in “Response to Arguments” (page 4) that both the support (2) of Higo and the sheet member (50) of the present application are made of the same material, a non-woven fabric. First, the claim does not limit the sheet member to a non-woven fabric. That is, the limitation on the structure of the sheet member is directed to the permeability of the gel, not the material of the sheet member. Second, even if sheet member is a non-woven material, not all non-woven materials have the same permeability to the gel. Even in this case, the claim limits which non-woven materials can be used for the sheet member.

The Examiner also points to Higo, col. 3, lines 7-21, and asserts the support (2) of Higo describes the permeability feature recited in the claims of the present application. The support (2) of Higo is not characterized in terms of permeability or the extent of permeability. The material for support (2) of Higo is only characterized as “material with excellent workability, flexibility and suitable shape retention and water retention . . . it is only necessary that the material have the effect mentioned above.” Higo, col. 3, lines 7-17. Certainly, there is no suggestion the support (2) is made of a material chosen to have permeability to a gel sufficient to retain the gel when a portion of the gel permeates therein.

In contrast, in the invention as claimed in claim 1, the sheet member is made of a material that the gel containing the drug can permeate. The partial permeation of the gel into the sheet member creates a retention force between the gel and the sheet member. Pub. App. pars. [0023], [0024] and [0026]. Thus, the present invention claims a particular composition of the sheet member to have a recited permeability to gel in the area to receive the gel. The “wherein” clause

characterizes the permeability property of the sheet member. That is, not only is the sheet member permeable to the gel containing the drug, the extent of permeability is sufficient to retain the gel in the device. It is part of Applicants' invention to combine a sheet member into which a gel containing the drug can permeate as part of the iontophoresis device. This characteristic of the recited composition of the sheet member at least distinguishes the present iontophoresis device from that disclosed in Higo.

Thus, claim 1 is patentable over Higo because that reference does disclose each and every element recited in the claim. In particular, Higo does not disclose a sheet member covering the electrode layer with the sheet member "having a property for allowing said gel to permeate therein . . . wherein, when said gel is disposed on said sheet member in the region to receive the gel, the property of the sheet member to allow the gel to permeate therein is sufficient to provide a retention force resulting from a permeated portion of the gel to retain the gel in the region to receive the gel" as recited in claim 1.

Even accepting, *arguendo*, the support (2) of Higo is permeable to the gel, that would only be the first property (1) of the sheet member of the present invention, discussed above. A second property (2), the extent of permeability is not disclosed in Higo. There is no disclosure in Higo of the support material being chosen to have a particular permeability, that is, sufficient for gel retention. Thus, even accepting the support of Higo is permeable to the gel containing the drug (which is not conceded), Higo still does not recognize nor place the limitation of restricting the extent of that permeability to achieve retention of the gel in the device.

Finally, the Office Action asserts, on page 4 (“Response to Arguments”) that Applicants have admitted that prior art teaches the claim 1 element, “a sheet member . . . having a property for allowing said gel to permeate therein . . . wherein, when said gel is disposed on said sheet member in the region to receive the gel, the property of the sheet member to allow the gel to permeate therein is sufficient to provide a retention force resulting from a permeated portion of the gel to retain the gel in the region to receive the gel.” This just is not so. Note the present invention has an electrode (conductive) layer (30) and a sheet member (50) (on the conductive layer). The Background of the present invention describes only a conductive layer made of a porous material, with the drug contained in the porous material. There is no admission of a separate sheet member having the permeability as recited in the claims. Applicants request a specific citation for the Office Action contention of the alleged admission.

For reasons similar or somewhat similar to those described above with regard to independent claim 1, independent claims 10 and 11 are also believed to be patentable.

### III. REJECTIONS UNDER 35 U.S.C. §103(a)

Claims 8 and 13 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Higo in view of U.S. Patent No. 6,731,987 to McAdams et al. (hereinafter, merely “McAdams”).

Applicants respectfully traverse this rejection.

Claims 8 and 13 depend from claims 1 and 11, respectively, and should be allowable for at least the same reasons as discussed above. McAdams does not add the feature missing from Higo.

#### IV. DEPENDENT CLAIMS

The other claims are dependent from one of the claims discussed above and are therefore believed patentable for at least the same reasons. Because each dependent claim is also deemed to define an additional aspect of the invention, however, the individual reconsideration of the patentability of each on its own merits is respectfully requested.

#### CONCLUSION

Claims 1-14 are in condition for allowance. In the event the Examiner disagrees with any of statements appearing above with respect to the disclosure in the cited reference, or references, it is respectfully requested that the Examiner specifically indicate those portions of the reference, or references, providing the basis for a contrary view.

Please charge any additional fees that may be needed, and credit any overpayment, to our Deposit Account No. 50-0320.

In view of the foregoing amendments and remarks, it is believed that all of the claims in this application are patentable and Applicants respectfully request early passage to issue of the present application.

Respectfully submitted,

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